



03-05-01

0300

Express Mail Label No.: EK611903379US

Date of Deposit: March 2, 2001

Attorney Docket No. 15966-599 (CURA-99)

#15

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

1645

APPLICANTS: Shimkets and Leach
SERIAL NUMBER: 09/718,321 EXAMINER: Not Yet Assigned
FILING DATE: November 22, 2000 ART UNIT: Not Yet Assigned
FOR: NUCLEIC ACIDS CONTAINING SINGLE NUCLEOTIDE POLYMORPHISMS AND
METHODS OF USE THEREOF

March 2, 2001
Boston, Massachusetts

Assistant Commissioner for Patents
Washington, D.C. 20231

TRANSMITTAL LETTER

RECEIVED

Sir:

AUG 01 2002

Transmitted herewith for filing in the present application are the following documents:

TECH CENTER 1600/2900

- ☒ Information Disclosure Statement (4 pages);
- ☒ Modified Form 1449/PTO duplicate copy (2 pages);
- ☒ Copies of Cited references: A1, B1-B8, C1-C25; and
- ☒ Return Postcard.

If the enclosed papers are considered incomplete, the Mail Room and/or the Application Branch is respectfully requested to contact the undersigned at 617/542-6000, Boston, Massachusetts.

No fee is believed to be due. However, if any fees are to be assessed, the Commissioner is hereby authorized to charge the balance due to the undersigned's account, Deposit Account No. 50-0311 (Reference 15966-599, CURA-99). A duplicate copy of this transmittal letter is enclosed.

Respectfully submitted,

Ivor R. Elrifi, Reg. No. 39,529
Shelby J. Walker, Reg. No. 45,192
Attorney(s) for Applicants
c/o MINTZ, LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

Express Mail Label No.: EK611903379US
Date of Deposit: March 2, 2001

Attorney Docket No. 15966-599 (CURA-99)



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

RECEIVED

AUG 01 2002

APPLICANTS: Shimkets and Leach

SERIAL NUMBER: 09/718,321

EXAMINER: Not Yet Assigned

FILING DATE: November 22, 2000

ART UNIT: Not Yet Assigned

FOR: NUCLEIC ACIDS CONTAINING SINGLE NUCLEOTIDE POLYMORPHISMS AND
METHODS OF USE THEREOF

TECH CENTER 1600/2900

March 2, 2001
Boston, Massachusetts

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, Applicants hereby make of record the documents listed below and on the attached modified Form PTO-1449 (submitted in duplicate) in the above-identified application, copies of which are submitted herewith. The order of presentation of the references should not be construed as an indication of the importance of the references.

U.S. Patent Documents:

<u>U.S. Patent Document No.</u>	<u>Name of Assignee</u>	<u>Filing Date</u>
5,856,104	Affymetrix, Inc.	March 7, 1997

Foreign Patent Documents:

<u>Patent Document No.</u>	<u>Name of Applicant</u>	<u>Date of Publication</u>
EP 0 717,113 A2	Affymax Technologies, N.V.	19-06-1966
WO 95/11995	Affymax Technologies, N.V.	4 May 1995
WO 93/22456	Trustees of Dartmouth College	11 November 1993
WO 98/14470	Genetics Institute, Inc.	9 April 1998
WO 98/20165	Whitehead Institute for Biomedical Research	14 May 1998
WO 98/56954	Affymetrix, Inc.	17 December 1998
WO 98/14466	Progentior, Inc.	9 April 1998
WO 97/19212	HP-Chemie Pelzer Research and Development Ltd.	29 Mai 1997

Other Prior Art – Non Patent Literature Documents:

- Abravaya, K., J. J. Carrino, et al. (1995). "Detection of point mutations with a modified ligase chain reaction (Gap- LCR)." Nucleic Acids Res 23(4): 675-82.
- Adams, M. D., J. M. Kelley, et al. (1991). "Complementary DNA sequencing: expressed sequence tags and human genome project." Science 252(5013): 1651-6.
- Barany, F. (1991). "Genetic disease detection and DNA amplification using cloned thermostable ligase." Proc Natl Acad Sci U S A 88(1): 189-93.
- Cotton, R. G., N. R. Rodrigues, et al. (1988). "Reactivity of cytosine and thymine in single-base-pair mismatches with hydroxylamine and osmium tetroxide and its application to the study of mutations." Proc Natl Acad Sci U S A 85(12): 4397-401.
- Evans, W. E. and M. V. Relling (1999). "Pharmacogenomics: translating functional genomics into rational therapeutics." Science 286(5439): 487-91.
- Faham, M. and D. R. Cox (1995). "A novel in vivo method to detect DNA sequence variation." Genome Res 5(5): 474-82.
- Fischer, S. G. and L. S. Lerman (1983). "DNA fragments differing by single base-pair substitutions are separated in denaturing gradient gels: correspondence with melting theory." Proc Natl Acad Sci U S A 80(6): 1579-83.
- Gibbs, R. A., P. N. Nguyen, et al. (1989). "Detection of single DNA base differences by competitive oligonucleotide priming." Nucleic Acids Res 17(7): 2437-48.
- Kren, B. T., B. Parashar, et al. (1999). "Correction of the UDP-glucuronosyltransferase gene defect in the gunn rat model of crigler-najjar syndrome type I with a chimeric oligonucleotide." Proc Natl Acad Sci U S A 96(18): 10349-54.
- Landegren, U., R. Kaiser, et al. (1988). "A ligase-mediated gene detection technique." Science 241(4869): 1077-80.
- Maskos, U. and E. M. Southern (1993). "A novel method for the parallel analysis of multiple mutations in multiple samples." Nucleic Acids Res 21(9): 2269-70.
- Myers, R. M., Z. Larin, et al. (1985). "Detection of single base substitutions by ribonuclease cleavage at mismatches in RNA:DNA duplexes." Science 230(4731): 1242-6.
- Newton, C. R., A. Graham, et al. (1989). "Analysis of any point mutation in DNA. The amplification refractory mutation system (ARMS)." Nucleic Acids Res 17(7): 2503-16. (ABSTRACT)
- Nikiforov, T. T., R. B. Rendle, et al. (1994). "Genetic Bit Analysis: a solid phase method for typing single nucleotide polymorphisms." Nucleic Acids Res 22(20): 4167-75.
- Orita, M., Y. Suzuki, et al. (1989). "Rapid and sensitive detection of point mutations and DNA polymorphisms using the polymerase chain reaction." Genomics 5(4): 874-9.
- Orita, M., H. Iwahana, et al. (1989). "Detection of polymorphisms of human DNA by gel electrophoresis as single-strand conformation polymorphisms." Proc Natl Acad Sci U S A 86(8): 2766-70.

Orum, H., P. E. Nielsen, et al. (1993). "Single base pair mutation analysis by PNA directed PCR clamping." Nucleic Acids Res 21(23): 5332-6. (ABSTRACT)

Rhodes, M., R. Straw, et al. (1998). "A high-resolution microsatellite map of the mouse genome." Genome Res 8(5): 531-42.

Saiki, R. K., P. S. Walsh, et al. (1989). "Genetic analysis of amplified DNA with immobilized sequence-specific oligonucleotide probes." Proc Natl Acad Sci U S A 86(16): 6230-4.

Syvanen, A. C., K. Aalto-Setälä, et al. (1990). "A primer-guided nucleotide incorporation assay in the genotyping of apolipoprotein E." Genomics 8(4): 684-92. (ABSTRACT)

Taillon-Miller, P., Z. Gu, et al. (1998). "Overlapping genomic sequences: A treasure trove of single-nucleotide polymorphisms [In Process Citation]." Genome Res 8(7): 748-54.

Thiede, C., E. Bayerdorffer, et al. (1996). "Simple and sensitive detection of mutations in the ras proto-oncogenes using PNA-mediated PCR clamping." Nucleic Acids Res 24(5): 983-4.

Wagner, R., P. Debbie, et al. (1995). "Mutation detection using immobilized mismatch binding protein (MutS)." Nucleic Acids Res 23(19): 3944-8.

Wallace, R. B., J. Shaffer, et al. (1979). "Hybridization of synthetic oligodeoxyribonucleotides to phi chi 174 DNA: the effect of single base pair mismatch." Nucleic Acids Res 6(11): 3543-57.

Youil, R., B. W. Kemper, et al. (1995). "Screening for mutations by enzyme mismatch cleavage with T4 endonuclease VII." Proc Natl Acad Sci U S A 92(1): 87-91.

This Information Disclosure Statement is being filed:

- ☐ within three months of the filing date of the National Application;
- ☐ within three months of the filing date of the entry of the National Stage, as set forth in 37 C.F.R. §1.491, in an International Application; or
- ☒ before the mailing date of a first Office Action on the merits in the above-identified case.

Accordingly, no fee or certification is required. 37 C.F.R. §1.97.

A copy of each of the above-identified information is enclosed unless otherwise indicated on the attached Form PTO-1449 (modified). It is respectfully requested that the Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims, and signs the enclosed form PTO-1449 to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application.

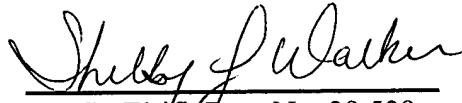
APPLICANTS:
U.S.S.N.:

Shimkets and Leach
09/718,321

By submitting this Information Disclosure Statement, the Applicant makes no representation that: (1) a search has been performed, of the extent of any search performed, or that more relevant information does not exist; (2) the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b); and (3) the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his/her own conclusion regarding the relevance of the cited information. An early and favorable action is hereby requested. Please charge any additional fees that may be due, or credit any overpayment of same, to Deposit Account No. 50-0311, Reference No. 15966-599 (CURA-99).

Respectfully submitted,



Ivor R. Elrifi, Reg. No. 39,529
Shelby J. Walker, Reg. No. 45,192
Attorney(s) for Applicants
c/o MINTZ, LEVIN
One Financial Center
Boston, Massachusetts 02111
Tel: (617) 542-6000
Fax: (617) 542-2241

TRADOCS:1443160.1(%XJS01!.DOC)